

<b>Case Number:</b>	CM13-0034141		
<b>Date Assigned:</b>	12/06/2013	<b>Date of Injury:</b>	02/27/2001
<b>Decision Date:</b>	03/18/2014	<b>UR Denial Date:</b>	09/26/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/17/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and Emergency Medicine and is licensed to practice in Florida. He/she has been in active clinical practice for more than five years and is currently working least at 24 hours a week in active practice. The physician reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This patient is a 44 year-old with a date of injury of 02/27/01. A progress report on 09/10 identified subjective complaints of low back pain radiating into the legs. She had tenderness of the lumbar spine, decreased range-of-motion, and a positive straight leg-raising test. Sensation was diminished in the L5 and S1 dermatomes bilaterally. Additionally, the patient has hemorrhoids and a fissure with frequent spread of infection for which she is treated with Flagyl and clindamycin. Diagnoses included postlaminectomy syndrome with bilateral radiculopathy as well as hemorrhoids. Treatment has included previous surgery, oral analgesics, and antidepressants. Specifically Norco, Cymbalta, Ambien, and Dendracin cream have been utilized in excess of 6 months. It is unclear how long the patient has been on antibiotics. A decision was rendered on 09/26/13 for non-certification of Flagyl 500mg # 30; Norco 10/325 mg # 240; Dendracin topical cream; Cymbalta 60mg; and Ambien 10mg.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Flagyl 500mg # 30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Hemorrhoids; Anal Fissures.

**Decision rationale:** Neither the Medical Treatment Utilization Schedule (MTUS) nor the Official Disability Guidelines (ODG) specifically address the treatment of hemorrhoids. No guidelines or authoritative sources recommend Flagyl for the treatment of hemorrhoids or anal fissures. Therefore, in this case, there is no documentation in the record for the medical necessity of Flagyl.

**Norco 10/325 mg # 240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-82. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids for Chronic Pain.

**Decision rationale:** NNorco 10/325 is a combination drug containing acetaminophen and the opioid hydrocodone. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. They further state that pain assessment should also include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. The guidelines note that a recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The Chronic Pain Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The Official Disability Guidelines (ODG) state: "While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective achieving the original goals of complete pain relief and functional restoration." The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. Likewise, therapy has continued well in excess of 16 weeks. Therefore, the record does not demonstrate medical necessity for Norco.

**Dendracin topical cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical; Salicylate Topicals; Topical Analgesics Page(s): 28-29, 105, 111-113.

**Decision rationale:** Dendracin cream has multiple ingredients that include methyl salicylate 30%, capsaicin, and menthol USP 10%. The strength of the capsaicin varies from 0.025% to 0.0375% by manufacturer. The MTUS Chronic Pain Guidelines state that topical analgesics are largely experimental and are primarily recommended for neuropathic pain. Specifically, the Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. However, salicylate is a non-steroidal anti-inflammatory agent. The Guidelines note that this class of topicals has not been shown to have long-term effectiveness. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The only FDA approved agent, diclofenac, has not been evaluated for treatment of the spine, hip or shoulder. They are not recommended for neuropathic pain as there is no evidence to support their use. Also, the Guidelines state that: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. Specifically, results of a randomized controlled trial support the use of the 0.025% formulation of capsaicin cream as first-line therapy for osteoarthritis pain. Capsaicin is available as a 0.025% formulation (for the treatment of osteoarthritis) and a 0.075% formulation primarily from studies for neuropathic pain. However, the Guidelines specifically state that: "... there have been no studies of 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy." In this case, Dendracin has been utilized beyond the short-term and there is no documented medical necessity for further use.

**Cymbalta 60mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta; SNRIs, Page(s): 13-16, 42, 105.

**Decision rationale:** Cymbalta (duloxetine) is an SNRI (serotonin norepinephrine reuptake inhibitor) class antidepressant. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines note that some antidepressants are: "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain (Feurstein, 1977) (Perrot, 2006)." The tricyclic agents are generally considered first-line unless they are ineffective, poorly tolerated or contraindicated. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in the use of other analgesics, sleep quality and duration as well as a psychological assessment. The optimal duration of therapy is not known. The Guidelines recommend that assessment of treatment efficacy begin at one week with

a recommended trial of at least 4 weeks. It is recommended that if pain is in remission for 3-6 months, a gradual tapering of the antidepressants occur. The long-term effectiveness of antidepressants has not been established. For neuropathic pain, tricyclic agents are recommended as first-line. Recent reviews also list tricyclics and SNRIs (duloxetine and venlafaxine) as first-line options. Antidepressants are listed as an option in depressed patients with non-neuropathic pain, but effectiveness is limited. The Guidelines note that non-neuropathic pain is generally treated with analgesics and anti-inflammatories. Multiple controlled trials have found limited effectiveness with antidepressants in fibromyalgia, with the exception of duloxetine. The Guidelines state that in low back pain: "... tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. SSRIs (selective serotonin reuptake inhibitors) have not shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition (Chou, 2007)." They further state that "SSRIs do not appear to be beneficial." No studies have specifically studied the use of antidepressants to treat pain from osteoarthritis. The Guidelines do note that in depressed patients with osteoarthritis, improving depression symptoms was found to decrease pain and improve functional status. The Guidelines state that tricyclic antidepressants specifically "... are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem." SNRIs are recommended as a first-line option for diabetic neuropathy. They note that there is no high quality evidence to support the use of duloxetine (SNRI) for lumbar radiculopathy. Related to SSRIs, the Guidelines state: "Selective serotonin reuptake inhibitors (SSRIs), a class of antidepressants that inhibit serotonin reuptake without action on noradrenaline, are controversial based on controlled trials (Finnerup, 2005) (Saarto-Cochrane, 2005). It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain (Namarka, 2004). More information is needed regarding the role of SSRIs and pain." Based on the lack of support for the efficacy of the SNRI class of antidepressants for fibromyalgia and lack of documentation for a diabetic neuropathy, there is no medical necessity documented for Cymbalta. Additionally, it is recommended that if pain is in remission for 3-6 months, a gradual tapering of the antidepressants should occur.

**Ambien 10mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anti-anxiety Agents in Chronic Pain.

**Decision rationale:** Ambien is a short-acting benzodiazepine hypnotic approved for short-term treatment of insomnia. The Medical Treatment Utilization Schedule (MTUS) states that benzodiazepines are "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence." Likewise, there is no recommendation for short-acting benzodiazepine hypnotics for any length of time. In this case, Ambien has had long-term use. Therefore, the record does not document the medical necessity for Ambien.